

Application No. 09/914,999  
Attorney Docket No. PG3619USW

# REMARKS / ARGUMENTS

Claims 1-30 remain in this application. Claims 1, 2, 13 have been amended to provide clear antecedent basis for the terms used, and to "Americanize" the spelling originally contained in the claims. Further, Claim 30 has been amended to recite subject matter falling within the scope of 35 USC §101.

In the 9/15/04 Official Action, Claims 14-24 were indicated to be allowable, but were objected to as being based on a rejected base claim. Claims 1-13, 25-26 and 28-30 were rejected as being anticipated by Mecikalski.

Applicant's note that the rejection failed to provide *any* explanation as to how exactly the claimed subject matter is met by the Mecikalski reference. The Official Action is therefore incomplete and improper, and contrary to the requirements of Chapter 700 of the MPEP. The examiner has provided no detailed explanation of how this reference discloses each element of the claimed invention assembled as required in the claims and has left the applicant to guess how to respond. The following is the applicant's attempt to respond in a meaningful fashion. Under the circumstances, any attempt at making a next office action final would also be considered improper.

US 5,568,807 to Mecikalski describes a tubular inhaler 9 incorporating a first valve 30 at the base of the inhaler and a second valve 32a and 32b at the opposite end of the inhaler where the mouthpiece 17 is located. Between these two valves is a chamber 31. The external wall of the chamber has a slot, through which a medicament pack 20 containing a powdered medicament 23 is inserted. The portion of pack 20 inside the chamber 31 has two holes 21a and 21b which provide access to and egress from the pack. As described in col. 4, line 38- col. 5, line 36, air entering the base of the inhaler passes through the first valve 30 and enters chamber 31. While in chamber 31, the airflow passes into the envelope 20, and powdered medicament is entrained in the airflow and drawn into the chamber 31 through hole 21b in the envelope 20. The entrained powder flows through chamber 31, and passes out of the inhaler through the check valve 32a and 32b in

Application No. 09/914,999  
Attorney Docket No. PG3619USW

mouthpiece 17. Note that neither the first valve 30 nor the check valve 32a/32b contact the envelope or the contents thereof.

**A. Claim 1 And All Claims Dependent Thereon Are Patentable**

Claim 1 recites, in pertinent part, recites:

*covering means characterized in that said covering means is in biased contact with said dose or container retaining the dose and only opens in response to airflow though and/or pressure drop across the airway in a first direction but not in a second, opposite direction.*

It is impossible to tell from the mere conclusory rejection of claim 1 what aspect of the Mecikalski reference the examiner believes fills this role. Micikalski lacks any cover means over the dose or dose container, and therefore nothing is "*in biased contact with said dose or container retaining the dose and only opens in response to airflow though and/or pressure drop across the airway in a first direction but not in a second, opposite direction.*"

In particular, neither valve 30 or 32a and 32b is in contact with the envelope 20 containing the medicament, and hence does not meet this requirement. The removeable layer 24 fails to correspond to this element as it is apparently removed prior to inserting the envelope 20 into the slot in the wall of chamber 31.

As the prior art does not teach each and every element of Claim 1, it does not render the claim anticipated. Each claim depending on claim 1 is patentable for the same reasons as claim 1.

Application No. 09/914,999  
Attorney Docket No. PG3619USW

Claim 5 depends on claim 1, and additionally recites an electronic element for sensing air flow. Mecikalski is completely silent as to this point. No case of anticipation can be established for this additional reason.

Claim 25 is dependent on claim 1 and additionally recites "a fixed seal". No fixed seal is disclosed in Mecikalski. For this additional reason, claim 25 is novel.

**B. Claim 13 And All Claims Dependent Thereon Are Patentable**

Independent claim 13 is the base claim for allowed claims 14-24. Claim 13 recites, in pertinent part:

*"A dose protector ...[comprising] at least one sealing flap in biased contact with said pocket and providing a cover for the pocket; wherein the contact between the at least one sealing flap and the pocket is broken by airflow through the airway in a first direction but not in a second opposite direction. (emphasis added).*

Mecikalski does not disclose *at least one sealing flap in biased contact with said pocket and providing a cover for the pocket*, let alone a sealing flap where *contact between the at least one sealing flap and the pocket is broken by airflow through the airway in a first direction but not in a second opposite direction*. In short, Mecikalski does not anticipate claim 13, as it does not recite each claimed element assembled as in the claim.

Withdrawal of the 102 objection of claim 13 over Mecikalski is therefore requested.

Application No. 09/914,999  
Attorney Docket No. PG3619USW

### CONCLUSION

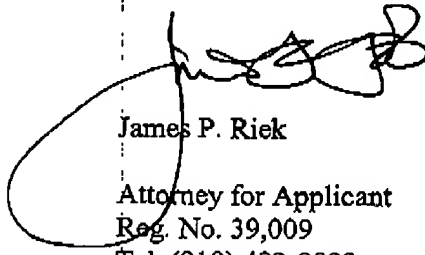
The Mecikalski reference fails to disclose each and every element of the claimed invention. Each of the pending claims is novel over this reference, and applicant's respectfully request withdrawal of all rejections.

All issued raised by the examiner to date have been addressed. As such, the claims are asserted to be in a condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted,

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